

REMARKS/ARGUMENTS

Claims 1-3, 7-28 and 30-33 are currently pending. Claims 1-3, 7-28 and 31-33 stand rejected. Claim 30 has been objected to by the Office. Claims 28 and 30 have been amended for clarity and no new matter has been added. No new claims have been added and no claims have been canceled herein. Applicants respectfully request reconsideration.

Rejection of Claims 1-3, 7-28 and 31-33 under 35 U.S.C. § 103(a)

Claims 1-3, 7-28 and 31-33 stand rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Williams (U.S. Pat. No. 5,429,582; hereinafter referred to as "Williams") in view of Tam et al (U.S. Pat. No. 6,458,069; hereinafter referred to as "Tam"). In order to support a rejection under 35 U.S.C. § 103(a), the rejected claims must be obvious in light of the cited reference. Because Applicants' claims 1-3, 7-28 and 31-33 are not obvious in light of Williams in view of Tam, Applicants traverse these rejections, at least for the following reasons.

Applicants independent claims 1, 18 and 26 recite, in relevant part, that the "...treatment agent is releasably mated with an outer surface of the expandable surface member...". Neither Tams nor Williams teach or suggest a treatment agent releasably mated with an outer surface of an expandable member, therefore Applicants fail to see any motivation to combine these references and further fail to see how the combination of these references could render Applicants claims 1, 18 and 26 obvious.

Tam does not teach or suggest a treatment agent releasably mated with an outer surface of the expandable surface member. Tam does not appear to teach or suggest any releasably mated treatment agents. The only treatment agent disclosed by Tam is the radioactive thin film source 10. The radioactive thin film source 10 taught by Tam is not releasably mated to an expandable member because it does not ever appear to release, detach or separate from the expandable member. It would be highly undesirable for the radioactive thin film source 10 to release or detach from the expandable member and permanently remain within the lumen of a patient. If the radioactive thin film source 10 were to be releasably mated it would leave a radioactive thin film 10 permanently inside the lumen of a patient, which would likely result in an undesirably high dosage of radiation in the lumen. Because the device disclosed by Tam could not operate in the same manner (i.e., using a releasably mated treatment agent) it would not provide the same therapeutic advantages, taught by Applicants claims 1, 18 and 26.

Williams also fails to disclose a treatment agent releasably mated with an outer surface of the expandable member, as recited in the Office Action dated 5/29/08, which states that,

"Williams discloses the claimed device and method except for the treatment agent being releasably mated with the expandable surface member." Because Tam does not teach the deficiencies of Williams (i.e., that the treatment agent is releasably mated with an outer surface of the expandable member), Applicants fail to see any motivation to combine the Tam and Williams references and assert that independent claims 1, 18 and 26 are in condition for allowance in their current form.

The Office Action dated 5/29/08 points to col. 7, lines 1-7 as disclosing "...using more than one treatment agent including radioactive and nonradioactive agents...". Applicants disagree with this interpretation of the teaching at col. 7, lines 1-7. While Tam does teach some nonradioactive components used to encapsulate or seal the device, these nonradioactive components are certainly not treatment agents and certainly would not have any therapeutic treatment value. The teaching at col. 7, lines 1-7 references use of a chemical attachment or "tie" layer 14 for binding the isotope, and an isotope species 16. The tie layer is used to denote a functional characteristic which enables securing of the isotope species 16 to the substrate 12, whether through the use of a discrete structure layer (such as an adhesive or functionally analogous component) or a surface modification to the substrate 12 (such as chemical activation). See col. 7, lines 45-50. This teaching in Tam is directed toward how the radioactive thin film source layer 10 is formed (as shown in FIGs. 1 and 1A), but certainly does not teach a nonradioactive treatment agent releasably mated, as taught by Applicants' dependent claim 3.

Applicants' specification teaches, "[t]he treatment agent preferably is layered on the surface of the expandable surface member 20 such that when the expandable surface member is expanded to contact tissue, at least part of the treatment agent is released." See Applicants' specification at paragraph [0024]. Applicants' specification goes on to teach an alternative embodiment in which the treatment agent is "released and/or diffuses out." See Applicants' specification at paragraph [0024]. Because the only treatment agent taught by Tam is a radioactive thin film source 10, and because the radioactive thin film source 10 is not releasably mated to the expandable member, Applicants fail to see how Tam teaches or suggests the deficiencies of the Williams reference. Applicants respectfully request the rejection of independent claims 1, 18 and 26 be withdrawn.

The Office Action dated 5/29/08 states that, "Tam et al also teaches that a treatment agent is releasably mated with the expandable member, by coating or disposing the treatment agent on all or a portion of the outer surface and the inner surface of the expandable member (column 17, lines 56-67). Applicants fail to see this teaching in Tam and further fail to find this teaching at column 17, lines 56-67. Applicants have not found any teaching or suggestion in Tam of a treatment agent releasably mated with an outer surface of the expandable member.

Tam, at column 17, lines 56-67, merely lists a number of different coating materials. Tam does not teach or suggest that these coating materials are treatment agents and does not teach or suggest that these components are releasably mated with an outer surface of the expandable member. Because Tam does not teach the deficiencies of Williams (i.e., that the treatment agent is releasably mated with an outer surface of the expandable member), Applicants fail to see any motivation to combine the Tam and Williams references and assert that independent claims 1, 18 and 26 are in condition for allowance in their current form.

To establish a *prima facie* case of obviousness, it is necessary for the Office to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985). Applying this standard to the references cited by the Office, it is clear that the Office has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Thus, a *prima facie* case of obviousness has not been established because the Office has not presented evidence that one having ordinary skill in the art would have been motivated to combine Tam with the teachings of Williams, to make the claimed invention.

Because there is no motivation to combine the Williams and Tam references, Applicants' independent claims 1, 18 and 26 are believed to be allowable over the combined teachings of Williams and Tam. Applicants' dependent claims 2, 3, 7-17, 19-25, 27, 28, and 31-33 are believed to be allowable, at least, because they depend from allowable independent claims 1, 18 or 26. Applicants respectfully request that the rejection of claims 1-3, 7-28 and 31-33 be withdrawn.

Objection to claim 30

Claim 30 has been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 30 has been amended to clarify dependency upon claim 26 and incorporate the limitations of former claim 29 (which was

previously canceled). Support for this amendment can be found, at least, in previously canceled claim 29.

Claim 30 is believed to be allowable in its current form, at least, because it depends from an allowable independent claim 26. Applicants incorporate their above arguments with regard to independent claim 26 and the Williams and Tam references, *supra*, and assert that claim 30 is in condition for allowance in its current form.

Conclusion

In light of the above Remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Office should have any questions or other issues to discuss, please do not hesitate to contact the undersigned attorney.

Applicants believe a Request for Continued Examination fee is required. Please consider this a Request for Continued Examination and charge Deposit Account No. 50-2855 accordingly. If any additional petitions or fees are necessary, please consider this a request therefore and authorization to charge Deposit Account No. 50-2855 accordingly. Any deficiency or overpayment may also be applied to Deposit Account No. 50-2855.

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Respectfully submitted,



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